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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,384	10/22/2003	Stephen P. Oliver	HME/7477.0017	8786

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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

MAIL DATE	DELIVERY MODE
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07/17/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/691,384

Applicant(s)

OLIVER ET AL.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,15,16,36-39,46 and 47 ~~is~~ are pending in the application.
- 4a) Of the above claim(s) 15, 16, 36-39, 46 and 47 ~~is~~ are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 ~~is~~ are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendment

- 1) Acknowledgment is made of Applicants' amendment filed 06/01/07 in response to the non-final Office Action mailed 03/08/07. With this, Applicants have amended the specification and the claims.

Status of Claims

- 2) Claims 3-14, 18-35 and 40-45 have been canceled via the amendment filed 06/01/07.
Claims 1, 2, 15, 17, 36, 37 have been amended via the amendment filed 06/01/07.
New claims 46 and 47 have been added via the amendment filed 06/01/07.
Claims 1, 2, 15-16, 36-39, 46 and 47 are pending.
Claims 1 and 2 are under examination.

The Oliver Declaration

- 3) Acknowledgment is made of Applicants' submission of the Oliver Declaration filed under 37 C.F.R. 1.132, which has been fully considered. See paragraph 20 below.

Prior Citation of Title 35 Sections

- 4) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

- 5) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Withdrawn

- 6) The objection to the specification made in paragraph 6(a) of the Office Action mailed 03/08/07 is withdrawn in light of Applicants' amendment to the specification.
- 7) The objection to the specification made in paragraph 6(b) of the Office Action mailed 03/08/07 is withdrawn in light of Applicants' amendment to the specification.
- 8) The objection to the specification made in paragraph 6(c) of the Office Action mailed

03/08/07 is withdrawn in light of Applicants' amendment to the specification.

9) The rejection of claims 1 and 2 made in paragraph 14 of the Office Action mailed 03/08/07 is withdrawn in light of Applicants' amendment to the claims.

Objection(s) Moot

10) The rejection of claims 3-5 and 11-14 made in paragraph 14 of the Office Action mailed 03/08/07 is moot in light of Applicants' cancellation of the claims.

Rejection(s) Moot

11) The rejection of claims 3-5 and 11-14 made in paragraph 7 of the Office Action mailed 03/08/07 under 35 U.S.C. § 112, first paragraph, as being non-enabled with regard to the scope, is moot in light of Applicants' cancellation of the claims.

12) The rejection of claim 11 made in paragraph 9(a) of the Office Action mailed 03/08/07 under 35 U.S.C § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.

13) The rejection of claims 3-5 and 12-14 made in paragraph 9(b) of the Office Action mailed 03/08/07 under 35 U.S.C § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claims.

14) The rejection of claim 11 made in paragraph 11 of the Office Action mailed 03/08/07 under 35 U.S.C § 102(b) as being anticipated by Drmanac *et al.* (WO 01/75067 – Applicants' IDS), is moot in light of Applicants' cancellation of the claim.

15) The rejection of claims 11 and 12 made in paragraph 12 of the Office Action mailed 03/08/07 under 35 U.S.C § 102(b) as being anticipated by Alexandrov *et al.* (EP 1033405), is moot in light of Applicants' cancellation of the claims.

16) The rejection of claims 3-5 and 11-14 made in paragraph 13 of the Office Action mailed 03/08/07 under 35 U.S.C § 102(b) as being anticipated by Park *et al.* (*In: Proceedings of the 40th Annual Meeting of National Mastitis Council*, National Council Incorporated, pages 247-248, February 2001), is moot in light of Applicants' cancellation of the claims.

Rejection(s) Withdrawn

17) The rejection of claims 1 and 2 made in paragraph 7 of the Office Action mailed 03/08/07

under 35 U.S.C. § 112, first paragraph, as being non-enabled with regard to the scope, is withdrawn in light of Applicants' amendment to the claims.

18) The rejection of claim 1 made in paragraph 9(a) of the Office Action mailed 03/08/07 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

19) The rejection of claim 1 made in paragraph 11 of the Office Action mailed 03/08/07 under 35 U.S.C § 102(b) as being anticipated by Drmanac *et al.* (WO 01/75067 – Applicants' IDS), is withdrawn in light of Applicants' amendment to the claim.

Rejection(s) Maintained

20) The rejection of claims 1 and 2 made in paragraph 13 of the Office Action mailed 03/08/07 under 35 U.S.C § 102(b) as being anticipated by Park *et al.* (*In: Proceedings of the 40th Annual Meeting of National Mastitis Council*, National Council Incorporated, pages 247-248, February 2001), is maintained for reasons set forth therein and herein below.

Applicants cite MPEP 2121.01 and contend that the disclosure in an assertedly anticipating reference must provide an enabling disclosure of the desired subject matter, and mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation. Applicants submit the Oliver Declaration under 37 C.F.R 1.132 and contend that additional experimental work was performed by the present inventors which culminated in the process disclosed in Example 6 of the instant application.

The Oliver declaration states that the reference of Park *et al.* does not provide an enabling disclosure by which a person of skill in the art would be able to make and use the claimed invention. The Oliver declaration further presents the following arguments:

(a) Park *et al.* compared two methods for the extraction of surface proteins from *Streptococcus uberis* and for the detection of lactoferrin-binding proteins (LBPs) within the multiplicity of extracted proteins. The first method reported by Galan & Timoney, 1985 is based on enzymatic degradation of the Gram positive cell wall followed by SDS-PAGE, transfer to nitrocellulose membrane, and detection of proteins using specific antibodies in a Western blot protocol. The second method is based on the use of SDS, which was adapted from the SDS-PAGE sample buffer formulation described by Laemmli *et al.* Proteins that were transferred onto

nitrocellulose were then detected through the use of specific antibodies that interacted specifically with the selected protein. In the methods described in Park's reference, a modification of the classical Western blot protocol was used in that lactoferrin (LF) and not specific antibody was used to detect bacterial proteins that bind LF. In both methods, the bacterial protein-LF complex was then detected by using antibodies produced in rabbits against LF.

(b) Following the extraction of bacterial surface proteins from *S. uberis*, either with SDS or mutanolysin, the surface proteins were electrophoresed by PAGE, which showed the presence of a large number of proteins of various sizes that were then probed with LF and detected on nitrocellulose membrane with antibodies against LF.

(c) The methods described in Park *et al.* detected LBP following extraction of bacterial surface proteins from the total protein pool in the bacterial cell wall. These methods do not result in purification of LBP, but only in a visible detection that LBP was within the extracted pool of bacterial surface proteins and within the region of 110 to 112 kDa that included this protein along with other bacterial surface proteins of comparable size. The declaration acknowledges that the LBP was 'extracted' from *S. uberis*, but argues that the LBP was not purified, which is allegedly emphasized in the last line of Park's disclosure.

(d) The declaration acknowledges that the procedure described in Park *et al.* is the same as that described in Example 4 of the present patent application, but argues that additional experimental work was required in order to obtain purified LBP, referred to in the instant application as SUAM. The declaration submits that Example 6 of the application describes the process that was developed to obtain purified SUAM from extracted *S. uberis* surface proteins.

(e) For a cited reference to anticipate a claimed invention, the reference must teach one skilled in the art how to make and how to use the claimed invention. Park *et al.* do not teach one skilled in the art how to make the claimed invention because the methods disclosed by Park *et al.* do not result in a purified protein that is SUAM. A significant amount of additional experimental work was required in order to obtain purified SUAM from extracted streptococcal surface proteins.

Applicants' arguments have been carefully considered, but are not persuasive. It should be noted that the instant claims that are under examination are *not* directed to a method of purifying SUAM protein from *S. uberis* using the steps described in Example 6 of the instant specification. Instead, the claims are directed to an isolated polypeptide comprising or consisting essentially of

SEQ ID NO: 4, which polypeptide is *not* required to be purified. The main argument in the declaration that the LBP was 'extracted' from *S. uberis* by Park *et al.*, but was not purified has been noted. The instant claims however are *not* directed to a purified polypeptide comprising or consisting essentially of SEQ ID NO: 4. Furthermore, the open claim language 'comprising' in claim 1 allows other proteins or contaminants being present with the claimed polypeptide. As readily acknowledged by the Oliver declaration, Park *et al.* taught the extracted LBP of *S. uberis*, referred to in the instant application as SUAM. One of the strains of *S. uberis* used by Park *et al.* for extraction of SUAM is ATCC 13387 strain of *Streptococcus uberis*, the identical *Streptococcus uberis* ATCC13387 strain used by Applicants. Parks' mutanolysin- or SDS-extracted *Streptococcus uberis* LBP (SUAM) is the same as Applicants' *Streptococcus uberis* SUAM that is isolated, since the prior art LBP has been isolated from the cellular mass of *Streptococcus uberis* and has been further subject to separation steps such as centrifugation, SDS PAGE, and transfer to nitrocellulose membrane etc. Clearly, Park *et al.* anticipate claim 1.

The addition of the limitation 'polypeptide consisting *essentially* of a polypeptide' in claim 2 has been noted. There is no indication in the instant specification of what is being excluded by the language 'polypeptide consisting *essentially* of a polypeptide'. Absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, 'consisting essentially of' is construed as equivalent to 'comprising'. See e.g., *PPG*, 156 F.3d at 1355, 48 USPQ2d at 1355 ('PPG could have defined the scope of the phrase 'consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention.'). Park's LBP polypeptide still anticipates claim 2. The rejection of claims 1 and 2 over Park *et al.* stands.

Remarks

21) Claims 1 and 2 stand rejected.

22) Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the

mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


23) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Central Fax number (571) 273-8300, which receives facsimile transmissions 24 hours a day and 7 days a week.

24) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

25) Any inquiry concerning this communication or earlier communication(s) from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail service. The Examiner can normally be reached on Monday to Friday from 7.15 a.m to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Jeffrey Siew, can be reached on (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.


S. DEVI, PH.D.
PRIMARY EXAMINER

July, 2007